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REMARKS

Upon entry of the amendment, claims 1-15, 19-30, 33-37, and 40-56 will be pending.

A. Regarding the Amendments

Claims 57, and 58 have been canceled without prejudice or disclaimer.

Claims 4 and 56 have been amended to correct obvious typographical errors. As such, it is submitted that the amendments do not add new matter.

Claim 37 has been amended to remove previously recited optional agents from the pharmaceutical composition. The amendment is supported, for example, by page 25, lines 4-6, which indicates that βCD can be used alone to reduce the risk of transmission of sexually transmitted diseases. As such, the amendment does not add new matter.

Claim 52 and 55 have been amended to clarify that the method further allows for the use of "a composition consisting essentially of" one or more of the recited agents. A such, the amendments clarify that the "further comprising" language of claims 52 and 55 indicates that a composition consisting essentially of one or more of the recited agents is contacted with the cells; i.e., a composition in addition to the pharmaceutical composition consisting essentially of a βCD (see claims 9 and 23).

It is submitted that the amendments do not require a new search or consideration because this matter has been of issue in this case, and was previously discussed with the Examiner. Further, it is submitted that the amendments place the application in condition for allowance, or in better condition for appeal. Accordingly, it is respectfully requested that the amendments be entered.

B. Claim Objections

Claims 57 and 58 were objected to because the numbering of claims allegedly is not in accordance with 37 CFR 1.126, which requires that original numbering of the claims be

preserved throughout the prosecution. Claims 57 and 58, which inadvertently were numbered 55 and 56, have been canceled herein. As such, it is submitted that the objection is moot, and respectfully requested that the objection of claims 57 and 58 be withdrawn.

C. Double Patenting Rejection

The provisional rejection of claims 1 to 15, 19 to 30, 33 to 37, and 40 to 51, under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1 to 4, 6 to 15, 19 to 20, 22 to 30, 33 to 37, and 40 to 45 of the copending application U.S. Serial No. 09/801,393 ("the '393 Application"), is respectfully traversed. Furthermore, the provisional rejection of claims 52 to 56 and 57 to 58, under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 16 to 18, 31 to 32, and 38 to 39 of the '393 Application is respectfully traversed.

A Terminal Disclaimer, disclaiming any term of a patent issuing from the subject application that may extend beyond the term of a patent issuing from the '393 Application is submitted herewith. Accordingly, it is respectfully requested that this provisional rejection of the claims be removed.

It is noted that, upon removal of the provisional double patenting rejection, there will be no outstanding rejection with respect to claims 1 to 15, 19 to 30, 33 to 36, and 40 to 45. As such, it is submitted that these claims, at least, are in condition for be allowance, and a Notice to that effect is respectfully requested.

D. Prior Art Rejections

Claim 37 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Bergeron et al. (U.S. Pat. No. 6,068,851) in view of Baert et al. (WO 97/18839), and Sokal et al. (U.S. Pat. No. 5,819,742). Applicant respectfully traverses the rejection.

It is alleged in the Office Action that Bergeron et al. teach compositions and methods for preventing the transmission of sexually transmitted pathogens through mucosae and/or skin, wherein the composition can act as a physical, chemical, or pharmacological barrier, and can be encapsulated in cyclodextrin (CD). Although it is acknowledged that Bergeron et al. do not teach 2-hydroxypropyl-βCD, the amounts of cyclodextrin used, or a CD composition being formulated into a suppository, film, condom, bioadhesive polymer, diaphragm, absorptive substrate, glove, sponge, or tampon, it is alleged that the deficiencies in Bergeron et al. are provided by the teachings of Baert et al. and Sokal et al. More specifically, it is alleged that Baert et al. teaches pharmaceutical compositions that include 2-hydroxypropyl-βCD and active ingredients including an antiviral agent. It is alleged that Sokal et al. teaches a vaginal device for providing physical and chemical barriers for protection against sexually transmitted diseases, that the device can have a formulation incorporated therein, and that the formulation can include one or more pharmacologically active agents.

As an initial matter, Applicant submits that one of ordinary skill in the art would not have been motivated to combine Sokal et al. with Bergeron et al. and/or Baert et al. As indicated in the Office Action, Sokal et al. describe a vaginal device that can include a pharmacologically active agent. However, prior to Applicant's disclosure, it was not known in the art that a βCD had a pharmacological activity, particularly an activity in reducing the risk of transmission of, or infection with, a sexually transmitted pathogen. Instead, βCDs only were known to be useful as carriers for active agents. Since there is nothing in Sokal et al. to indicate that a βCD is an active agent and, as discussed below, nothing in Bergeron et al. or Baert et al. to teach or suggest a βCD as an active agent, one of ordinary skill would have had no motivation to combine Sokal et al. with either or both of Bergeron et al. and Baert et al. Accordingly, it is respectfully requested that Sokal et al. be removed as relevant prior art and that any rejections based, in part, on Sokal et al. be removed.

Notwithstanding the above, it is submitted that the cited references, when considered alone or in combination, would not have rendered a pharmaceutical composition "consisting essentially of" a βCD obvious to one of ordinary skill in the art. To establish a *prima facie* case of obviousness there must be some suggestion or motivation in the prior art to make the claimed invention, there must be a reasonable expectation of success, and the prior art reference must teach or suggest all of the claim limitations. MPEP § 2142; In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claim 37 as amended, is directed to "a pharmaceutical composition consisting essentially of a β-cyclodextrin, which reduces the risk of transmission of a sexually transmitted pathogen". As such, it is clear from the plain language of the claim that the βCD in the composition is the active ingredient with respect to reducing the risk of such transmission. Applicant maintains that the cited references, either alone or in combination, do not teach or suggest the claimed composition because, prior to the present disclosure, it was not known that a βCD can reduce transmission of a sexually transmitted pathogen; βCDs only were known in the art as solubilizing agents or as carriers of pharmaceutically active compositions. As such, there is nothing in the art that would have led one to prepare a pharmaceutical composition "consisting essentially of" a βCD. In this respect, Bergeron et al. refer to the use of cyclodextrins as an encapsulating agent for inhibitors such as HIV protease and reverse transcriptase inhibitors (see, e.g., column 3, line 67, to column 4, line 11). However, Bergeron et al. do not teach or suggest that CDs such as a βCD has any pharmacological activity.

Baert et al. do not cure the defect of Bergeron et al. because Baert et al. merely describe combining a βCD with an active ingredient such as loviride, which is an anti-retroviral agent. However, Baert et al. do not teach or suggest that a βCD is an "active agent" or the preparation of a pharmaceutical composition consisting essentially of a βCD, which reduces the risk of transmission of a sexually transmitted pathogen. Further, even if for argument sake the Sokal et

al. reference is considered, Sokal et al. do not even mention CDs such as a βCD and, therefore, cannot provide that which is missing in Bergeron et al. and Baert et al.

In summary, the cited references do not teach or suggest that a βCD has any pharmacological activity, and specifically do not teach or suggest that a βCD reduces the risk of transmission of a sexually transmitted pathogen. As such, the claimed compositions would not have been obvious to one of ordinary skill in the art and, therefore, it is respectfully requested that the rejection of claim 37 under 35 U.S.C. § 103(a) be removed.

Claims 52 to 56 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Bergeron et al. (U.S. Pat. No. 6,068,851) in view of Baert et al. (WO 97/18839). Applicant respectfully traverses the rejection.

It is alleged in the Office Action that Bergeron et al. teach compositions and methods for preventing the transmission of sexually transmitted pathogens through mucosae and/or skin, wherein the composition can act as a physical, chemical, or pharmacological barrier, and can be encapsulated in cyclodextrin (CD). Although it is acknowledged that Bergeron et al. do not teach 2-hydroxypropyl-βCD, or a cyclodextrin as an active agent, it is alleged that the deficiencies in Bergeron et al. are provided by the teachings of Baert et al. More specifically, it is alleged that Baert et al. teaches pharmaceutical compositions that include 2-hydroxypropyl-βCD and active ingredients including an antiviral agent and, therefore, that it would have been obvious to use a βCD in the method of Bergeron et al., because βCDs were taught by Baert et al. for pharmaceutical compositions, which are useful for treating HIV-infected patients.

It is stated in the Office Action (page 14, first full paragraph) that, while the claims recite the term "consisting essentially of", for purposes of prior art, the term is construed as "comprising" absent a clear indication in the specification as to the basic and novel characteristics of the claimed invention (citing to MPEP § 2111.03). As discussed in the Interview with the Examiner held February 5, 2003, and noted in the Amendment filed March 21,

2003, the specification discloses that βCDs are active in preventing transmission of a sexually transmitted pathogen (see, for example, page 5, lines 6-23; page 8, lines 10-20; and page 25, lines 1-7; see, also, page 26, line 18, to page 27, line 3). Thus, the specification clearly discloses the basic and novel characteristics of the claimed methods and composition, i.e., that a βCD has activity in reducing the risk of transmission of or infection with a sexually transmitted pathogen. Accordingly, it is submitted that, with respect to the claimed methods, recitation of the term "consisting essentially of" in claim 9, from which claims 52 to 54 depend, and claim 23, from which claims 55 and 56 depend, should be read as indicating that the pharmaceutical composition used in the method contains only βCD as the active ingredient.

With respect to claims 52 to 56, it is noted that claim 52, which depends from claim 9, and claim 55, which depends from claim 23, have been amended to more clearly indicate that the claimed methods can "further comprise" contacting the pathogen or cells with a composition "consisting essentially of" one or more of the recited agents. Thus, the claims as amended clarify that the claimed methods require the use of a pharmaceutical composition consisting essentially of a βCD (claims 9 and 23), and further allow for the use of an additional composition consisting essentially of one or more of the recited agents (claims 52 to 56); the claims do not allow for the use of a pharmaceutical composition containing, in a single formulation, a βCD and another active agent.

It is submitted that the cited references, when considered alone or in combination, would not have rendered the claimed methods obvious to one of ordinary skill in the art. To establish a *prima facie* case of obviousness there must be some suggestion or motivation in the prior art to make the claimed invention, there must be a reasonable expectation of success, and the prior art reference must teach or suggest all of the claim limitations. MPEP § 2142; In re Vaeck, 947 F.2d 488, 20 USPQ2d, 1438 (Fed. Cir. 1991). The cited references, either alone or in combination, do not teach or suggest the claimed methods because, prior to Applicant's disclosure, it was not

known that βCD had a pharmacological activity; cyclodextrins, including βCDs, were only known in the art as solubilizing agents or as carriers of pharmaceutically active compositions. In this respect, Bergeron et al., which is cited in support of the present rejection, refer to the use of "cyclodextrins" as an encapsulating agent for "inhibitors" such as HIV protease and reverse transcriptase inhibitors (see, e.g., column 3, line 67, to column 4, line 11). However, Bergeron et al. do not teach or suggest that CDs such as a βCD has any pharmacological activity. Baert et al. do not cure the defect of Bergeron et al. because Baert et al. merely describe combining a βCD with an active ingredient such as loviride, which is an anti-retroviral agent. However, Baert et al. do not teach or suggest that a βCD is an "active agent." Accordingly, the cited art does not teach or suggest a method that includes the use of a pharmaceutical composition that contains only a βCD as the active ingredient and, therefore, it is respectfully requested that the rejection of claims 52 to 56 under 35 U.S.C. § 103(a) be removed.

Claims 57 and 58 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Bergeron et al. (U.S. Pat. No. 6,068,851) in view of Baert et al. (WO 97/18839). Applicant respectfully traverses the rejection. Claims 57 and 58 are canceled herein, without prejudice. Therefore, the rejection of claims 57 and 58 is rendered moot. Accordingly, Applicant respectfully requests removal of the rejection of claims 57 and 58 under 35 U.S.C. § 103(a).

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. In particular, it is noted that, pursuant to the Terminal Disclaimer filed herewith, all pending rejections of claims 1 to 15, 19 to 30, 33 to 36, and 40 to 45 have been overcome. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Check No. 545401 in the amount of $55.00 is enclosed for the Terminal Disclaimer fee. No other fees are necessary for the filing of this Amendment. However, the Commissioner is hereby authorized to take any additional fees, or make any credits, to Deposit Account No. 50-1355. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

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